

## **Intravenous Zanamivir Requests for Severely Ill Hospitalized Patients**

For hospitalized influenza patients with suspected or known gastric stasis, gastric malabsorption, gastrointestinal bleeding, or for patients suspected or confirmed with oseltamivir-resistant influenza virus infection, intravenous zanamivir should be considered.

There are currently two ways to obtain IV zanamivir: enrollment in a clinical trial through a clinical site, or through a compassionate use request through Glaxo Smith Kline with FDA approval.

For information about potential enrollment in an IV zanamivir clinical trial, see:  
<http://www.clinicaltrials.gov/ct2/show/NCT01014988?term=zanamivir&rank=3>

**To request IV zanamivir for compassionate use, the requesting clinician should first call GSK at:**

GSK Clinical Support Help Desk:

Phone: **919-315-5215**

Email: [gskclinicalsupportHD@gsk.com](mailto:gskclinicalsupportHD@gsk.com)

Availability is 7 days a week, 24 hours/day, including holidays.

GSK will provide information on obtaining IV zanamivir, assess eligibility for clinical trials, and provide the EIND forms that need to be completed for FDA approval if compassionate is requested for IV zanamivir for EIND is requested.

\*The EIND paperwork does not need to be completed before contacting FDA and FDA granting an EIND request, so a requesting clinician should contact GSK first, and then quickly contact FDA.

**To contact FDA:**

To request FDA EIND approval for IV zanamivir during weekday work hours (8 AM - 4:30 PM EST), clinicians should call FDA at: 301-796-1500.

**To request FDA EIND approval specifically for IV zanamivir after regular business hours, the requesting clinician should call: 301-796-9900 (nights or weekends).**

**Some selected references for IV zanamivir:**

Dulek DE, Williams JV, Creech CB, Schulert AK, Frangoul HA, Domm J, Denison MR, Chappell JD. Use of intravenous zanamivir after development of oseltamivir resistance in a critically ill immunosuppressed child infected with 2009 pandemic influenza A (H1N1) virus. *Clin Infect Dis*. 2010 Jun 1;50(11):1493-6.

Gaur AH, Bagga B, Barman S, Hayden R, Lamptey A, Hoffman JM, Bhojwani D, Flynn PM, Tuomanen E, Webby R. Intravenous zanamivir for oseltamivir-resistant 2009 H1N1 influenza. *N Engl J Med*. 2010 Jan 7;362(1):88-9.

Härter G, Zimmermann O, Maier L, Schubert A, Mertens T, Kern P, Wöhrle J. Intravenous zanamivir for patients with pneumonitis due to pandemic (H1N1) 2009 influenza virus. *Clin Infect Dis*. 2010 May 1;50(9):1249-51.

Kidd IM, Down J, Nastouli E, Shulman R, Grant PR, Howell DC, Singer M. H1N1 pneumonitis treated with intravenous zanamivir. *Lancet*. 2009 Sep 19;374(9694):1036.